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CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

December 7, 2000

Dockets Management Branch
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Re: Citizen Petition No. 97P-0079

Dear Sir or Madam:

Pursuant to 21 C.F.R. § 10.30(d), the Consumer Healthcare Products Association (CHPA) submits these comments in opposition to the above-captioned citizen petition and in support of the comments filed by Novartis Consumer Health, Inc. (Novartis) on October 17, 2000. The citizen petition asks FDA, among other things, to deny Novartis three years of market exclusivity under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) in connection with the switch of Habitrol® (nicotine transdermal system) from prescription to nonprescription status. It appears that FDA already has denied exclusivity to Novartis for the Habitrol switch but may reconsider the issue after reviewing the comments submitted to this citizen petition docket, which remains open.

CHPA is the 119-year old national trade association that represents manufacturers and distributors of nonprescription, or over-the-counter (OTC), drugs and dietary supplements. CHPA members account for more than 90 percent of the retail sales of OTC drugs in the United States.

CHPA believes that it is vital for FDA to maintain a regulatory environment conducive to the appropriate switch of drugs from prescription to OTC use. The denial of

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exclusivity for Habitrol violates the statute and the agency's own internal guidelines for granting exclusivity, and undermines the incentives for conducting research and development activities in support of new switch candidates. This, in turn, will make fewer medicines available to the American public for self-care. Accordingly, CHPA urges FDA to deny the citizen petition and grant exclusivity to Novartis.

Rather than repeating the detailed legal and factual analysis presented by Novartis, these comments will briefly summarize the most important principles from an overall policy standpoint and apply them to the Habitrol situation.

A. Policy Considerations

Market exclusivity is a vital incentive for switch. The research and development process for switch candidates is lengthy and expensive. Unless manufacturers can be assured of an adequate return, they cannot be expected to invest the time and money needed for this effort. The availability of a three-year market exclusivity period under the Hatch-Waxman Act during which follow-on abbreviated applications cannot be approved (21 U.S.C. § 355(j)(5)(D)(iii) and (iv)) is a critical part of the investment calculation. FDA should interpret and apply the exclusivity provisions in a way that will advance the public policy in support of switching drugs to OTC status that can be safely and effectively used as part of a self-care regimen without a prescription.

FDA must provide reliable guidance in advance on whether exclusivity will be available. In order to make rational investment decisions, companies need to know, with a high degree of certainty, whether exclusivity will be available *before* they commit funds to switch

efforts. The key issue typically is whether clinical studies are essential to approval of the switch (*id*; 21 C.F.R. § 314.108). The perception that FDA may require studies at the outset yet decide at the end that they were not "essential" after all creates apprehension about the availability of exclusivity and thereby skews the analysis away from switch efforts. It is, moreover, fundamentally unfair for FDA to reverse course and deny exclusivity after a company has made substantial investment decisions in reliance on agency guidance as to what was necessary.

FDA must adhere to proper administrative processes in making exclusivity decisions. The agency must notify the manufacturer of a possible adverse decision on exclusivity, provide a clear statement of the basis for the proposed decision, and provide an opportunity for a response before the final decision is made. These are basic elements of administrative procedure that are necessary to ensure rational, consistent agency decisionmaking, to provide a fair opportunity for the manufacturer to have notice and be heard, and to form the basis for judicial review. FDA has been criticized in the past for its failure to develop a proper administrative record in support of the denial of exclusivity for a switch. *See Upjohn Co.* v. *Kessler*, 938 F. Supp. 439, 442 (W.D. Mich. 1996) (court was "appalled" at the poor state of the administrative record tendered by FDA); *see generally, e.g., A.L. Pharma, Inc.* v. *Shalala*, 62 F.3d 1484, 1491 (D.C. Cir. 1995) (agency record must be sufficient to demonstrate that it engaged in "reasoned decisionmaking").

B. Application to Habitrol

The denial of exclusivity for Habitrol violates each of the policy principles set forth above.

FDA's decision to deny exclusivity appears to rest on a determination that the dosing regimen for Habitrol is "not significantly different" from the regimen for another nicotine patch that had been switched. This is not a standard that appears in the statute and cannot legally be the basis for denying exclusivity. Moreover, it invites post hoc, subjective judgments rather than rational, consistent decisions. This concern is underscored here, where FDA (correctly) granted exclusivity to other switched nicotine replacement therapy products yet denied it for Habitrol. *See* Letter from Janet Woodcock, M.D. to Gary Yingling (Oct. 31, 1996) (concluding that clinical studies conducted in accordance with FDA guidance were essential to approval of Nicorette switch). *See generally, e.g., Independent Petroleum Ass'n* v. *Babbitt*, 92 F.3d 1248, 1258 (D.C. Cir. 1996) ("agency must treat similar cases in a similar manner unless it can provide a legitimate basis for failing to do so"). The various nicotine replacement products approved through full new drug applications are not therapeutic equivalents, and data on one therefore cannot suffice to demonstrate the safety and effectiveness of another.

Novartis reasonably believed on the basis of the FDA guidance that clinical studies were essential to the approval of the Habitrol switch. The company had no advance notice that FDA might conclude otherwise after it had invested in conducting the studies, filing a switch application, and seeing it through to approval. It is just this kind of unfair, post hoc

change that injects so much uncertainty into the process and thereby undermines incentives for switch.

Finally, Novartis received no formal notice of the denial of its exclusivity request, and the administrative record consists merely of handwritten checkmarks, cross-outs, and notations that are internally inconsistent and utterly fail to explain the agency's decision. Indeed, the checklist used by FDA was filled out in a manner that should have led the agency to grant rather than deny exclusivity. It is disturbing that, four years after the *Upjohn* decision cited above, FDA is still following such a fundamentally flawed process.

Conclusion

Taken together, FDA's departures from the statute, sound policy, and proper administrative procedures unlawfully restrict the circumstances in which exclusivity will be available for switches and increase the uncertainty surrounding the issue. Thus, the incentives for research and development of switch candidates will be reduced, to the detriment of the American consumer. For these reasons, CHPA urges FDA to deny the citizen petition and to grant exclusivity to Novartis in connection with the Habitrol switch.

Respectfully submitted,

Eve E. Bachrach
Senior Vice President, General Counsel and Secretary

cc: Janet Woodcock, M.D. (HFD-001)
Margaret Porter, Esq. (GCF-1)